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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/913,667 | 01/22/2002 | Lance A Liotta | 4239-60680 | 5252 |
| 36218 | 7590 | 03/15/2004 | EXAMINER | |
| KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET, SUITE #1600 ONE WORLD TRADE CENTER PORTLAND, OR 97204-2988 | | | MINNIFIELD, NITA M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,667

Applicant(s)

LIOTTA ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28,34-39,44-51 and 53-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28,34-39,44-51 and 53-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/16/01.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-28, 34-39, 44-51 and 53-83 in Paper No. December 11, 2003 is acknowledged.
2. Applicants' amendment filed December 11, 2003 is acknowledged and has been entered. Claims 29-33, 40-43 and 52 have been canceled. Claims 1-28, 34-39, 44-51 and 53-83 are pending in the present application.
3. The Office acknowledges Applicants' request for acknowledgement of priority applications (part of 12/11/03 paper). The Office notes that 60/120288 filed 2/16/99 was listed in the Oath and Declaration. The Examiner will forward Application to the clerical area to have benefit of 60/120288 filed.
4. The disclosure is objected to because of the following informalities: letters missing from words, for example see page 7 line 27; page 23, line 1; the title on page 24; missing letters in heading on page 31, line 26. Applicants are encouraged to review the entire specification for such errors and the appropriate correction is required.
5. Claims 2, 4-11, 16, 19, 25-28, 47, 76 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2 and 16 are vague and indefinite in the recitation of "small volume"; what are the metes and bounds? Claims 4-11 lack positive antecedent basis in the

recitation of “the protein sample”; is this the same as the “isolated protein samples” recited in claim 1, line 5”? Claims 16 and 25-28 are indefinite because they contain the abbreviations that have not been defined. Full terminology should be in each instance in the claims without the additional use of redundant abbreviations in parentheses or otherwise. Claim 19 lacks positive antecedent basis in the recitation of “immunoassay”. Claim 47 lacks positive antecedent basis in the recitation of “calibrating”. Claims 76 and 81 are vague and indefinite in the recitation of “which is used as to calibrate”; what does Applicant intend?

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-28, 34-39, 44-51 and 53-83 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonner et al (6251516).

The applied reference has a common inventor (Liotta and Emmert-Buck) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Bonner et al discloses a method of microdissection and analyzing proteins of interest (abstract). Bonner et al discloses methods and devices for the microdissection and molecular analysis of cellular samples, which may be used in combination with a number of different technologies that allow for analysis of proteins from substantially pure populations or subpopulations of particular cell types (col. 1, l. 20-26; col. 2, l. 62-64; col. 4, l. 15-26; col. 6, l. 23-32; col. 8, l. 39-42; col. 8; col. 19). Bonner et al discloses improved methods to specifically examine genetic alterations in pre-invasive lesions of common epithelial tumors such as breast and prostate carcinoma (col. 2, l. 35-40). Bonner et al discloses that the proteins or cells of interest can be analyzed, visualized or identified by a variety of labels, histochemical stains, antibodies, etc (col. 4, l. 31-38). Bonner et al discloses that one or more cells of interest can be isolated via laser capture microdissection; abnormal cells or control cells (i.e. normal) can be obtained (cols. 10-11). Example 1 discloses collection and analysis of normal and tumor tissue (see cols. 20-21 and Table 1). Example 4 discloses analysis of normal and human prostate cancer (col. 23) and Example 5 discloses analysis of breast carcinomas (col. 25). The prior art anticipates the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 1-3, 8, 12, 13, 15-17 and 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Olsen et al (Neuroendocrinology, 1989, 50/4:392-399) Abstract only.

Olsen et al discloses methods of analyzing proteins tissue samples from mice brain. The proteins from the three microdissected areas were separated by two dimensional gel electrophoresis, the gels were silver stained and analyzed by quantitative computerized scanning densitometry. The prior art anticipates the claimed invention. Since the Patent Office does not have the facilities for examining and comparing applicants' methods with the methods of the prior art reference, the burden is upon applicants to show a distinction between the material structural and functional characteristics of the claimed methods and the methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. No claims are allowed.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

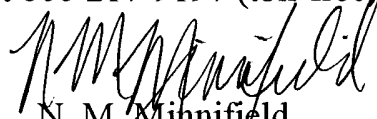
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The

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fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

March 8, 2004